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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/501,714	02/10/00	AU-YOUNG J	PF-0309-3 DI

HM22/1204

Incyte Pharmaceuticals Inc
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EXAMINER	
SLOBODYANSKY,E	
ART UNIT	**PAPER NUMBER**
1652	8

DATE MAILED: 12/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/501,714	Applicant(s) Au-Young et al.
	Examiner Elizabeth Slobodyansky	Group Art Unit 1652

☒ Responsive to communication(s) filed on *Sep 25, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *43-61 and 65-68* is/are pending in the application.

Of the above, claim(s) *43, 44, 50, 51, and 57-61* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *45, 47-49, 52-56, and 65-68* is/are rejected.

☒ Claim(s) *46* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The amendment filed September 25, 2000 canceling claims 62-64 and amending claims 45, 49 and 57 and adding claims 66-68 has been entered.

Claims 66-68 are rejoined with claims 45-49, 52-56 and 65.

Claims 43-61 and 65-68 are pending.

Claims 45-49, 52-56 and 65-68 are under consideration, claims 43, 44, 50, 51 and 57-61 are withdrawn.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 49 ultimately depend from claim 45 that does not encompass biologically-active and immunogenic fragments of SEQ ID NO:1 or SEQ ID NO:3 unless they do not have 90% sequence identity to the sequence of SEQ ID NO:1 or SEQ ID NO:3.

Claim Rejections - 35 USC § 112

Claims 45, with dependent claims 47-49 and claim 52, with dependent claims 53-56 and 66-68, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules with either SEQ ID NOS: 2 or 4; or DNA having the limitations of encoding a protein having the SEQ ID NOs: 1 or 3; or any DNA which is 90% identical to SEQ ID NOs:2 or 4; or encodes a protein that is 90% identical to SEQ ID NOs:1 or 3.

This rejection is reiterated from the office action mailed June 21, 2000.

In their Remarks filed September 25, 2000 Applicants argue that "it would be routine and without undue experimentation to determine whether a naturally occurring sequence thus obtained is a sequence that is 90% identical to the sequence of SEQ ID NO:2 or SEQ ID NO:4. No doubt, such variants my be many in number, but it would not

be an impractical or undue task to identify such variants" (page 5, last paragraph). These arguments address the enablement rejection and therefore are not persuasive to overcome the written description rejection.

The claims are further drawn to a vast diverse genus of a DNA encoding a polypeptide comprising a biologically-active or immunogenic fragment of SEQ ID NO:1 or SEQ ID NO:3 or comprising at least 16, 20, 30 or 60 contiguous nucleotides of said sequences. This genus includes many structurally and functionally unrelated DNAs.

The specification does not disclose structural, physico-chemical or biological characteristics of a polypeptide comprising a biologically-active or immunogenic fragment of SEQ ID NO:1 or comprising at least 16, 20, 30 or 60 contiguous nucleotides. The specification does not teach correlation between the structure and the function of the genus. Therefore, based on the instant disclosure, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of a DNA encoding a polypeptide comprising a fragment of SEQ ID NO:1 or SEQ ID NO:3 or a DNA encoding a polypeptide comprising a sequence having 90% identity to SEQ ID NO:1 or SEQ ID NO:3 and a fragment thereof. Thus, a DNA encoding a polypeptide comprising a sequence having 90% identity to SEQ ID NO:1 or SEQ ID NO:3 and a fragment thereof and a DNA encoding a polypeptide comprising a fragment of SEQ ID NO:1 or

SEQ ID NO:3 lack sufficient written description needed to practice the invention of claims 45, 47-49, 52-56, 66-68.

Claims 49, 53-56 and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding a polypeptide of SEQ ID NO:1 or SEQ ID NO:3, does not reasonably provide enablement for a DNA encoding a polypeptide comprising a biologically-active or immunogenic fragment thereof or a fragment of a 90% identical sequence having no known function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a DNA encoding a polypeptide comprising a biologically-active or immunogenic fragment of SEQ ID NO:1 or SEQ ID NO:3 or comprising at least 16, 20, 30 or 60 contiguous nucleotides of said sequences or 90% identical sequences.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the

art, (7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any sequence that comprises a fragment of SEQ ID NO:1 or SEQ ID NO:3 or of 90 % identical sequence because the specification does **not** establish: (a) regions of the protein structure which may be modified without effecting the specific requisite activity of the polypeptide encoded by a DNA of the instant invention; (B) the general tolerance of said polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement.

The state of the art does not allow the predictability of the properties based on the structure. The properties of a polypeptide of an unknown length and structure are unpredictable based on a fragment. Therefore, one skilled in the art would require

guidance as to how to use a DNA encoding a polypeptide of unknown function comprising fragments of SEQ ID NO:1 or SEQ ID NO:3 or of 90% identical sequences. in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is indefinite because "biologically-active fragment" does not define the function of said fragment. a fragment may exhibit various different functions such as catalytic, regulatory, immunogenic, etc. Fragments possessing any of these functions are not necessarily the same. Therefore, without pointing out the function there is no way of knowing what are the metes and bounds of the claim.

Claims 65, 67 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: in claims 65 and 68, a probe used for detecting is not defined; in claim 67 compounds used in polymerase chain reaction are not defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45, 52 and 53 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al.(accession N93316).

Hillier et al. (accession N93316) teach an EST of 482 bp that has 99.2% identity to nucleotides 817-1298 of SEQ ID NO:2.

Claims 45, 52 and 53 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al.(accession W63690).

Hillier et al (accession W63690) teach an EST of 661 bp that has 93.6% identity to nucleotides 23-618 of SEQ ID NO:4.

Claims 45, 52 and 53 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al.(accession AA020916).

Hillier et al (accession AA020916) teach an EST of 646 bp that has 94.6% identity to nucleotides 26-638 of SEQ ID NO:4.

Claims 45, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Weissenbach et al.

Weissenbach et al (accession Z52396) teach a 332 bp DNA fragment that is 95% identical to nucleotides 1093-1211 of SEQ ID NO:2.

The above sequences comprise at least 60 contiguous nucleotides of SEQ ID NO:2 or SEQ ID NO:4 as required by claim 53. Claim 52 is included in this rejection because a naturally-occurring sequence is not limited to 90% sequence identity to the full-length SEQ ID NO:2 or SEQ ID NO:4. Claim 45 is rejected because the above DNA encode a biologically active fragment of SEQ ID NO:2 or SEQ ID NO:4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54 and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Hillier et al. (accession N933160, accession W63690, accession AA020916) or Weissenbach et al. (accession Z52396).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the EST discussed above in hybridization assays with or without the amplification step and for screening of test compounds. The motivation and expectations of success are provided by the state of the art in which hybridization assays and screening of libraries is an intended use of ESTs.

Double Patenting

Claims 45-49, 52 and 53 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 5,922,567 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Claims 45-49, 52 and 53 are rejected under the judicially created doctrine of double patenting over claims 1-9 of U. S. Patent No. 6,001,598 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

This rejection is reiterated from the office action mailed June 21, 2000.

In their Remarks filed September 25, 2000 Applicants argue that "polynucleotides in the instant application are of different scope than the allowed claims of the issued patent " (page 17, 1st paragraph). While it is agreed that they are of different scope, said polynucleotides are still covered by issued patents and therefore, a terminal disclaimer is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

December 1, 2000